MAY 1 3 2004

K040990

# TAB 2 – Summary of Safety and Effectiveness

**510(k) Summary (per 21 CFR 807.92(c))**



## SUBMITTER

Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, FL 32218
FDA Registration No. 1032347

## PRODUCT NAME

Common/Usual Name: Radiographic Marker

Proprietary Name: Self-Drilling Radiographic Marker

## DEVICE CLASSIFICATION

The FDA has cleared radiographic markers via 510(k) Premarket Notification as Product Code NEU and Classification number 878.4300: Marker, Radiographic, Implantable – Class II. No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for implantable radiographic markers.

## PREDICATE DEVICE

The predicate device is the Stainless Steel Self Drilling Radiographic Marker cleared under W. Lorenz 510(k) number K014148 on January 17, 2002.

## DESCRIPTION OF DEVICE

The Self-drilling Radiographic Markers are zirconium bone screws used as radiographic markers, and may be implanted into bone during orthopedic or other surgical procedures. These devices are used to measure movement of implants after surgery with the aid of an X-ray. Self-drilling Radiographic Markers are applied with manual surgical instruments.

## INTENDED USE OF THE DEVICE

The Self-Drilling Radiographic Markers are zirconium screws indicated for use as radiographic markers and may be implanted into bone during orthopedic or other surgical procedures. These devices are used to measure movement of implants or serve as a reference point to locate anatomical structures with the aid of an X-ray.

## STATEMENT OF COMPARISON OF TECHNOLOGICAL FEATURES

Both the new and the old devices consist of non absorbable material (stainless steel, zirconium) listed in FDA's Biomaterials Compendium and list of FDA recognized standards. Both the predicate devices and the modified devices are implanted into bone during surgical procedures to radiographically mark a surgical location (e.g. implant, prosthesis, or anatomic position). The metallic materials and intended use as radiographic markers are technically equivalent.

## CONCLUSIONS

The use of modified zirconium screws and the predicate stainless steel screws as radiographic markers is substantially similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 3 2004

Ms. Kim Reed
Senior Regulatory Specialist
W. Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K040990
Trade/Device Name: Self-Drilling Radiographic Markers
Regulation Number: 21 CFR 878.4300
Regulation Name: Marker, radiographic, implantable
Regulatory Class: II
Product Code: NEU
Dated: April 14, 2004
Received: April 16, 2004

Dear Ms. Reed:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K040990

# Indications for Use

510(k) Number (if known): K040990

Device Name: Self-Drilling Radiographic Markers

Indications For Use:

Self-Drilling Radiographic Markers are used as radiopaque markers and may be implanted into bone during orthopedic or other surgical procedures. These devices are used to measure movement of implants or serve as a reference point to locate anatomical structures with the aid of an X-ray.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**



**510(k) Number** K040990